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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,599	02/05/2004	Andrew S. Kende	176/60813 (6-11400-728)	5421

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,599

Applicant(s)

KENDE ET AL

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 18-25 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 10/29/04 in response to the non-final Office Action mailed 09/09/04. With this, Applicants have amended the specification.

Status of Claims

- 2) Claims 16, 17 and 22 have been amended via the amendment filed 10/29/04.
Claims 16-25 are pending.
Claims 16 and 17 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the title made in paragraph 6 of the Office Action mailed 09/09/04 is withdrawn in light of Applicants' amendment to the title.
6) The objection to the specification made in paragraph 7 of the Office Action mailed 09/09/04 is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Withdrawn

- 7) The rejection of claims 16 and 17 made in paragraph 9(a) of the Office Action mailed 09/09/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.
8) The rejection of claim 16 made in paragraph 9(c) of the Office Action mailed 09/09/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
9) The rejection of claim 16 (not claim 17 as indicated inadvertently in the Office Action) made in paragraph 9(d) of the Office Action mailed 09/09/04 under 35 U.S.C § 112, second paragraph, as

being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claim 17 made in paragraph 9(e) of the Office Action mailed 09/09/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim

11) The rejection of claim 16 made in paragraph 9(f) of the Office Action mailed 09/09/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

12) The rejection of claim 16 made in paragraph 9(b) of the Office Action mailed 09/09/04 under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein. The identified recitation in lines 1 and 2 of claim 16 has not been corrected or amended. It is suggested that Applicants replace the limitation 'a Gram negative bacteria autoinducer' in lines 1 and 2 of claim 16 with the limitation --an autoinducer of a Gram negative bacterium--.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claims.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

13) Claim 16 and the claim dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 16, as amended, includes the new limitation 'fragment thereof' (see line 3). However, while there is descriptive support at lines 6-8 of page 28 of the specification for 'functionally active fragments thereof', there is no descriptive support for the now added broad limitation: 'fragment thereof'. Therefore, the above-identified new limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

14) Claim 16 and the claim dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 16, as amended, includes the new limitations: 'detecting whether binding between the antibody, or fragment thereof, and the autoinducer of the Gram negative bacterium occurs, wherein said binding indicates presence of the autoinducer in the sample'. There is no descriptive support for the above-identified limitations in the specification, as originally filed. Therefore, the above-identified new limitations in the claim(s) are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

15) Claims 16 and 17 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 16 is confusing in the limitation: 'the autoinducer of a Gram negative bacterium according to Formula (I)'. For clarity, it is suggested that Applicants replace the limitation with --the autoinducer of the Gram negative bacterium having Formula I--.

(b) Claim 16 lacks proper antecedent basis in the limitation 'fragment thereof' in the third line from the bottom of the claim. For proper antecedence, it is suggested that Applicants replace the limitation with --the fragment thereof--.

(c) Claim 17 is vague and confusing in the use of what appears to be the improper Markush limitation: 'selected from the group of' as opposed to the language --selected from the group consisting of--.

(d) Claim 17, which depends from claim 16, is also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Objection(s)

16) Claim 16 is objected to for the following reasons:

- (a) The limitation 'fragment' in line 3 of claim 16 currently lacks a preceding article.
- (b) For clarity, in line 1 of claim 16 immediately below the chemical formula, it is suggested that Applicants replace the limitation 'where' with the limitation --wherein--.

Remarks

17) Claims 16 and 17 stand rejected.

This application contains claims drawn to an invention non-elected with traverse. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. 1.144) MPEP § 821.01.

18) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (571) 272-8300.

20) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

21) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

January, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER